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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/851,882	05/09/2001	Dipak Ghosh	210556	4321

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EXAMINER	
YU, GINA C	

ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 02/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/851,882	GHOSH ET AL.	
	Examiner	Art Unit	
	Gina C. Yu	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 April 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-68* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-68* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Receipt is acknowledged of amendment, remarks, and declaration filed on April 23, 2004. Claims 1-68 are pending. Claim rejection made under 35 U.S.C. § 112, second paragraph, is withdrawn in view of claim amendment made by applicants. Claim rejections made under 35 U.S.C. § 103 (a) are withdrawn and modified to address the newly added claims. The substance of the rejections of is maintained for the reasons of record.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

1. Claims 1-13, 17-29, and 32-68 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hoppe et al. (US 5889062) in view of Raab (Uses of Urea in Cosmetology, 1990).

Hoppe teaches composition comprising ubiquinones for treating senile xerosis, of which the symptoms include dryness, cracking, roughness skin by providing moisture to the skin. See col. 1, line 9 – col. 2, line 37. The reference teaches preferably using 0.2-0.4 by weight of coenzyme Q10. See col. 3, lines 4 – 15. The reference also teaches that the active compound can be present in the topical formulations in amounts of 0.001-50 % by weight of the formulations. See col. 3, lines 39 – 48. See instant claims 47-54 and 56-68. The composition is formulated in W/O or O/W emulsion gel, lotion, or cream. See col. 3, lines 16 – 20; col. 4, lines 53- 60. The additives including emulsifiers, preservatives, buffer substances, thickeners, frangrances, antioxidants,

vitamins, and UV protection filters are also to be added in the composition. See col. 3, line 21 – col. 4, line 48. See Examples III-V for the amount. The reference teaches using 0.1-10 wt % of the UV protection filters. See col. 4, lines 36 – 46.

Hoppe fails to teach adding urea.

Raab teaches the use of urea in concentrations of 4-10 wt % in cosmetic and/or dermatological compositions to provide moisturizing, desquamating, antimicrobial, and anti-inflammatory action to the skin. See p. 97, col. 2 – p. 98, col. 1. See instant claims 43-46 and 55. The reference teaches urea increases the therapeutic activity of other pharmaceutical substances, and in Table 3 shows the use of urea in combination with anti-inflammatory agents (glucocorticoids), trentinoin or others in the weight ratio of 10: 0.3 to 10: 5. See p. 101, first column; see instant claims 25-27. The reference recommends formulating urea-containing compositions in the form of emulsion lotion or cream, meeting instant claims 2, 3, and 38. See p. 102, col. 2.

It is generally considered prima facie obvious to combine two compounds each of which is taught by the prior art to be useful for the same purpose, in order to form a composition which is to be used for the very same purpose. The idea for combining them flows logically from their having been used individually in the prior art. See In re Kerkhoven, 626 F.2d 848, 205 USPQ 1069 (CCPA 1980). As shown by the recited teachings, the instant claims define nothing more than the concomitant use of two skin care actives conventionally used for dry skin treatment. It would follow that the recited claims define prima facie obvious subject matter.

It would have been further obvious to one having ordinary skill in the art at the time the invention was made to have modified the Hoppe invention by adding urea as motivated by Raab because of an expectation of successfully producing a topical composition for treating skin disorders including senile xerosis, with enhanced moisturizing property and improved pharmaceutical effects of other skin care actives.

2. Claims 1-12, 14, 15, 17, 19, 20, 21, 23, 24, 29, 30, 34, 35, 38, 39, 40, 41, 43-46, and 54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Eucerin Q10 Anti-Wrinkle product package and English translation of Eucerin press release (Eucerin Pressemitteilungen, Oct. 2000) in view of Business Wire (Feb. 1, 1999), Bertelli (US 4654373) and FDC Reports (October 26, 1992).

Eucerin product packages indicates that the composition comprises water, coenzyme Q10, glycerin (moisturizer), hydrogenated coco-glycerides (solid emollient), caprylic/capric triglyceride (oil), biosaccharide gum-1 (thickener), carbomer (thickener), parabens (preservatives), titanium dioxide (sunscreen), and sodium hydroxide (base neutralizer), and tocopheryl acetate (vitamin E, an antioxidant). See instant claims 1-12, 14, 15, 17, 19, 20, 21, 23-27, 29, 30, 34, 35, 38, 39, 40, and 41.

Eucerin press release teaches that the product has been available in the market since October 2000 by Beiersedorf.

Eucerin product package and press release fail to disclose the amount of coenzyme Q10 nor teach adding urea in the composition.

Business Wire teaches that it is well known in the art that Beiersdorf uses Q-pharma's coenzyme Q10 platform technology, which is described in Bertelli (US 4654373), in topical use non-prescription products. See Full Text.

Bertelli teaches the method of formulating and topically applying pharmaceutical or cosmethological pastes, creams, ointments, gels, lotions, or unguents which comprises 0.1-10 % Coenzyme Q10 to treat damaged and impaired skin tissue. See col. 2, lines 28 – 64.

While the Bertelli reference further suggests adding other topical actives in the composition, see col. 2, lines 61 – 64, the combined references above fail to teach adding urea in the Eucerin composition.

FDC Reports teaches that Beiersdorf produces a dry skin treatment composition comprising 5 % of urea under the tradename Eucerin Plus. See p. 14, 1st par. – 4th par. The reference teaches that the product "induces significant improvements in skin dryness and appearance relative to an untreated control". See Id.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the Eucerin anti-wrinkle treatment composition by adding 5 % of urea as motivated by Bertelli and FDC Reports, because of an expectation of successfully producing an enhanced skin treatment composition which moisturizes and treats damaged and impaired skin. The motivation to use coenzyme Q10 in the weight amount of 0.1-10 % by weight of the total composition is found in the combined teachings of Beiersdorf press release, Business Wire, and Bertelli. The

claimed methods in claims 43-46 and 54 of providing moisturizing property to the skin are viewed obvious uses of the prior art cosmetic compositions.

3. Claims 13, 16, 18, 22, 28, 31, 32, 33, 36, 42, 47-53, and 55-68 are rejected under 35 U.S.C. 103(a) as being unpatentable over Eucerin product package, Eucerin press release, Business Wire, Bertelli, and FDC Reports as applied to claims 1-12, 14, 15, 17, 19, 20, 21, 26, 27, 29, 30, 34, 35, 38, 39, 40, 41, 43-46, and 54 as above, and further in view of Hoppe.

The combined references fail to teach the amount of the additives and auxiliary ingredients.

Hoppe, discussed above, teaches emulsion formulations comprising coenzyme Q10 and additives. The reference also teaches incorporating coenzyme Q10 in topical formulations in the claimed amounts of instant claims 47-54 and 56-68.

Given the teaching the additives and auxiliary ingredients used in the Eucerin formulations as shown in the combined references, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have looked to the prior art such as Hoppe for the amounts of these additives in topical formulations. Furthermore, differences in concentration generally will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. See MPEP § 2144.05. Since the general conditions of the instant claims are disclosed in the combined references, examiner views that one having ordinary skill in the art would have discovered the optimum or workable ranges by routine experimentation to formulate a topically applicable, stable composition.

4. Claims 23-25 and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Eucerin product package, Eucerin press release, Business Wire, Bertelli, FDC Reports, and Hoppe as applied to claims 1-22, 26-36, 38-45 as above, and further in view of Raab.

While Eucerin product package teaches that the composition is designed for sensitive skin crème, the combined references above fail to teach adding soothing agents.

Raab, discussed above, teaches urea formulations comprising anti-inflammatory agents (glucocorticoids) in the weight ratio of 10: 0.3 to 10: 5. See p. 101, first column; see instant claims 25-27.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the composition of the combined references by adding soothing agents such as glucocorticoids as motivated by Raab because of an expectation of successfully producing a topical composition effective to treat irritated skin.

Oath/Declaration

Applicant's declaration filed under 37 C.F.R. § 1.131 was fully considered, but does not place the application in allowable condition. Applicants seek to establish that the combining urea and coenzyme Q10 in claimed weight ratio and weight amount produces greater than expected moisturizing effects by measuring the "moisturisation value" of the skin of five panelists, using a Nova DPM 9003 meter. According to the comparison graph, at hour 3, coenzyme Q10 alone is said to achieve about 12 % while

urea alone achieves 11 % of the "moisturisation value". The declaration indicates that a composition comprising 0.3 % of urea and 0.05 % of coenzyme Q10 produces about 23.5 % of moisturization value, which is viewed as a mere additive effect of the two moisturizing active ingredients.

At hour 4, coenzyme Q10 and urea still produce about 7.5 % and 10.5 % of the moisutrization value, while the combined composition produces about 26 % (additive value ≈18%). Examiner is mindful that unexpected results can be shown by the evidence of synergistic effects. However, a greater than additive effect is not necessarily sufficient to overcome a prima facie case of obviousness because such an effect can either be expected or unexpected. See MPEP § 716.02(a)(I). Applicants must further show that the results were greater than those which would have been expected from the prior art to an unobvious extent, and that the results are of a significant, practical advantage. See Ex parte The NutraSweet Co., 19 USPQ2d 1586 (Bd. Pat. App. & Inter. 1991) (Evidence showing greater than additive sweetness resulting from the claimed mixture of saccharin and L-aspartyl-L-phenylalanine was not sufficient to outweigh the evidence of obviousness because the teachings of the prior art lead to a general expectation of greater than additive sweetening effects when using mixtures of synthetic sweeteners.). In this case, Raab teaches to use urea in cosmetic compositions not only for moisturizing action, but also for "enhancement of the penetration and/or activity of other drugs". See 98. The reference also teaches the significant increase of moisturizing activity of urea when added to the glycerol/water control. See p.98, second col. – p. 100, first col.; p. 99., Figures 3 and 4. Thus

enhanced activity of other drugs, such as coenzyme Q10 in this case, is generally expected, and the data showing the moisturizing value of the two components is not sufficient to overcome the evidence of obviousness.

Response to Arguments

Applicant's arguments filed on April 23, 2004 have been fully considered but they are not persuasive.

Applicants assert that Hoppe and Raab fail to teach that coenzyme Q10 and urea are taught to be useful for the same purpose. In respond, examiner respectfully points out that Hoppe teaches the moisturizing properties of ubiquinones and Raab teaches the moisturizing effect of urea. Coenzyme Q10 is particularly mentioned in Hoppe. Thus the references establish that both coenzyme Q10 and urea are well known active ingredients for dry skin treatment.

The combined teachings of the references render a reasonable expectation of successfully making a topical composition with moisturizing effects because 1) both Hoppe and Raab teach to make formulations in the form of emulsion, lotion, or cream; and 2) the references teach the claimed weight amount and ratio of the two active ingredients. Hoppe teaches using 0.2-4 % by weight of coenzyme Q10, while Raab teaches using urea in concentration 4-10 % by weight. The claimed weight ratio of urea to coenzyme Q10, 6:1-10:1 is met by combining the two active ingredients as taught by the references.

As for the obviousness rejection made in view of Eucerin Q10 Anti-Wrinkle product package, Eucerin press release, Business Wire, Bertelli, and FDC reports,

applicants point out the deficiencies of the each reference but is silent as to why it would have been nonobvious to combine coenzyme Q10 and urea in view of these references. The collective teachings of EucerinQ10 Anti-Wrinkle product package, Eucerin press release, Business Wire, and Bertelli teach that a composition comprising coenzyme Q10 has been available in the market. FDC reports also teaches that the same company which produces Eucerin Q10 Anti-Wrinkle product also produces a dry skin treatment composition under the same tradename comprising urea, wherein urea is the active ingredient. Thus it would have been obvious to a skilled artisan that the combination of the two ingredients would produce a dry skin treatment composition.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gina C. Yu whose telephone number is 571-272-0635.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Gina Yu
Patent Examiner

SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER